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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,731	01/06/2006	Else Marie Agger	PLOUG8.001APC	1203

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
02/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/563,731	AGGER ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 14, 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6,7,9 and 11-25* is/are pending in the application.

4a) Of the above claim(s) *12,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,7,9,11,13-15 and 18-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/8/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 18, 2009 and January 14, 2010 has been entered.

Amendment Entry,

2. The amendment filed December 18, 2010 was not entered and non-compliant. The amendment filed January 14, 2010 has been entered. Claims 1, 9, and 15 have been amended. Claims 3-5, 8, and 10 have been cancelled. Claims 24-25 are new. Claims 1-2, 6-7, 9, 11-25 are pending. Claims 1-2, 6-7, 9, 11, 13-15, 18-25 are under examination. Claims 12 and 16-17 are withdrawn from consideration.

Information Disclosure Statement

3. The information disclosure statement filed on 1/8/2010 has been considered. An initialed copy is enclosed.

Withdrawal of Rejection

4. The rejection of claims 8 and 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in light of applicants cancellation of claims.

5. The rejection of claims 1, 4, 6-7, 10-11, and 13 under 35 U.S.C. 102(b) as being anticipated by Liu et al (US Patent Application 20020044951 Date April 18, 2002) is withdrawn in light of applicants amendment thereto and in light of applicants cancellation of claims 4 and 10.

6. The rejection of claims 1, 4, 6-11, 13 and 15 under 35 U.S.C. 103(a) as being unpatentable by Liu et al (US Patent Application 20020044951 Date April 18, 2002) and

Anderson et al (US Patent Application 20020176867 Date November 28, 2002) is withdrawn in light of applicants amendment thereto and in light of applicants cancellation of claims 4 and 10.

7. The rejection of claims 1, 2, and 14 under 35 U.S.C. 103(a) as being unpatentable by Liu et al (US Patent Application 20020044951 Date April 18, 2002) and Ravindranath et al (US Patent No. 6,218,166 US Publication Date April 17, 2001) is withdrawn in light of applicants amendment thereto.

8. The rejection of claims 18-23 (Liu et al US Patent Application 20020044951 Date April 18, 2002), Andersen et al (Infection and Immunity Vol. 62 No. 6, 1994 pgs. 2536-2544), Anderson et al (US Patent Application 20020176867 Date November 28, 2002), and Lowrie et al (US Patent Application 20020198168 Date December 26, 2002) is withdrawn in light of applicants arguments.

Response to Arguments

9. Applicant's arguments with respect to claims 1-2, 6-7, 9, 11, 13-15, 18-25 have been considered but are unpersuasive for the reasons set forth in the rejections below.

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The rejection of claims 18-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter rejection) is maintained for the reasons set forth in the previous office action. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant arguments:

Applicants arguments filed in response to the 35 U.S.C. 112 first paragraph, December 18, 2009 is carefully considered, but not found to be persuasive for the reasons below.

Applicant point to paragraphs [0043], [0123], [0014], [0055], [0025], [0020], [0038], [0028], [0029] regarding an immunogenic composition comprising an adjuvant and a antigen for support for the phrase "are drawn to an immunogenic composition comprising an adjuvant and a tuberculosis antigen, wherein said adjuvant comprises a solution prepared from an evaporated mixture of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent (claim 18); wherein said tuberculosis antigen comprises ESAT6-Ag85B hybrid or a fragment thereof (claim 19)".

Examiner's Response to Applicant's Arguments:

As to independent claim 18, said claim recites the limitation "adjuvant comprises a solution prepared from an evaporated mixture of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanum and a solvent" . Even though the specification discloses paragraphs [0043], [0123], [0014], [0055], [0025], [0020], [0038], [0028], [0029] regarding an immunogenic composition comprising an adjuvant and a antigen as claimed, there is no support provided in the written description of the specification stating a solution prepared from an evaporated mixture of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent. Therefore, it is apparent, that Applicants were not in possession of the claimed adjuvant at the time of filing. Applicants pointing to the specification by page and line number where specific written description for said recitation set forth supra may resolve this issue.

As outlined previously, the claims recite the phrase "are drawn to an immunogenic composition comprising an adjuvant and a tuberculosis antigen, wherein said adjuvant comprises a solution prepared from an evaporated mixture of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent (claim 18); wherein said tuberculosis antigen comprises ESAT6-Ag85B hybrid or a fragment thereof (claim 19)". Although Applicant filed an explanation in the Applicants Arguments/Remarks on 12/10/2008 stating support (see paragraphs 0010, 0016, 0020, 0029, 0039, and 0079) for the recitation set forth supra, these portions of the specification do not provide either explicit or implicit support for said limitation. Therefore, it is apparent, that Applicants were not in possession of the claimed recitations as set forth supra at the time of

filing. Applicants pointing to the specification by page and line number where specific written description for the recitation set forth supra may resolve this issue. This is a new matter rejection.

11. The rejection of claims 20-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter rejection) is maintained for the reasons set forth in the previous office action. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant arguments:

Applicants arguments filed in response to the 35 U.S.C. 112 first paragraph, December 18, 2009 is carefully considered, but not found to be persuasive for the reasons below.

Applicant point to paragraphs [0043], [0123], [0014], [0055], [0025], [0020], [0038], [0028], and [0029] for support for the phrase "consisting essentially of a resuspension of an evaporated mixture of a solvent, a surfactant selected from the group consisting of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent (claim 20), comprising a tuberculosis antigen (claim 21), wherein said tuberculosis antigen comprises ESAT6-Ag85B hybrid or a fragment thereof (claim 22), wherein surfactant is DDA (claim 23)".

Examiner's Response to Applicant's Arguments:

As to independent claim 20, said claim recites the limitation "a resuspension of an evaporated mixture of a solvent, a surfactant selected from the group consisting of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent". Even though the specification discloses paragraphs [0043], [0123], [0014], [0055], [0025], [0020], [0038], [0028], and [0029], there is no support provided in the written description of the specification stating a resuspension of an evaporated mixture of a solvent, a surfactant selected from the group consisting of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent. Therefore, it is apparent, that Applicants were not in possession of the claimed adjuvant at the time of filing.

Applicants pointing to the specification by page and line number where specific written description for said recitation set forth supra may resolve this issue.

As outlined previously, the claims recite the phrase "consisting essentially of a resuspension of an evaporated mixture of a solvent, a surfactant selected from the group consisting of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent (claim 20); comprising a tuberculosis antigen (claim 21), wherein said tuberculosis antigen comprises ESAT6-Ag85B hybrid or a fragment thereof (claim 22), wherein surfactant is DDA (claim 23)". Although Applicant filed an explanation in the Applicants Arguments/Remarks on 12/10/2008 stating support (see paragraphs 0010, 0016, 0020, 0029, 0039, and 0079) for the recitation set forth supra, these portions of the specification do not provide either explicit or implicit support for said limitation. Therefore, it is apparent, that Applicants were not in possession of the claimed recitations as set forth supra at the time of filing. Applicants pointing to the specification by page and line number where specific written description for the recitation set forth supra may resolve this issue. This is a new matter rejection.

New Claim Objections

12. Claim 2 is objected to because of the following informalities: trehalose is misspelled. Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1, 2, 6-7, 11, 13-15, and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable by Liu et al (US Patent Application 20020044951 Date April 18, 2002), Dascher et

al (International Immunology Vol. 15, No. 8, January 2003 pgs. 915-925), Ravindranath et al (US Patent No. 6,218,166 US Publication Date April 17, 2001), and Lindbald et al (Infection and Immunity Vol. 65 No. 2, 1997 pgs. 623-629).

The claims are drawn to an adjuvant comprising dimehtyldioctadecylammonium-bromide, -chloride, -phosphate, or -acetate (DDA) and an apolar fraction or part of the apolar fraction of a total lipid extract of a mycobacterium (claim 1), wherein the part of the apolar fraction of the lipid extract is selected from the group consisting of phthiocerol dimycocerosates, trehalose mycolipenates, glycosylated phenol phthiocerols, thehalose mycolates, sulfolipids, triacylglycerols and menaquinones (claim 2), a vaccine comprising the adjuvant (claim 6), wherein said vaccine is formulated for parenteral, oral or mucosal administration (claim 7), a delivery system comprising the adjuvant (claim 11), wherein said mycobacterium is *BCG, M. microti, M. tuberculosis or M. vaccae* (claim 13), wherein glycosylated phenol phthiocerols are phenolic glycolipids (claim 14), wherein said mycobacterium is selected from the group consisting of *M. tuberculosis, M. bovis and M. africanum* (claim 15), an immunogenic composition comprising dimehtyldioctadecylammonium-bromide, -chloride, -phosphate, or -acetate (DDA) and an apolar fraction or part of the apolar fraction of a total lipid extract of a mycobacterium, wherein said composition comprises an antigenic component comprising an antigenic epitope (claim 24), an immunogenic composition comprising the adjuvant (claim 25).

Liu et al teach an adjuvant comprising surfactants and an apolar fraction or part of total lipid extract of a mycobacterium (see abstract, [0031], [0059]). Lui et al teach a vaccine comprising the adjuvant, wherein vaccine is formulated for parenteral, oral or mucosal administration (see 0048, 0054). Liu et al teach a delivery system comprising an adjuvant (see 0045). Liu et al teach composition comprising an antigen isolated from *M. tuberculosis* (see abstract). Liu et al teach an adjuvant wherein mycobacterium is *M. tuberculosis* (see claims).

Lui et al does not teach an adjuvant comprising dimehtyldioctadecylammonium-bromide, -chloride, -phosphate, or -acetate (DDA), wherein the part of the apolar fraction of the lipid extract is selected from the group consisting of phthiocerol dimycocerosates, trehalose mycolipenates, glycosylated phenol phthiocerols, thehalose mycolates, sulfolipids, triacylglycerols and menaquinones, wherein glycosylated phenol phthiocerols are phenolic glycolipids, an immunogenic composition comprising dimehtyldioctadecylammonium-bromide,

-chloride, -phosphate, or -acetate (DDA) and an apolar fraction or part of the apolar fraction of a total lipid extract of a mycobacterium, wherein said composition comprises an antigenic component comprising an antigenic epitope, an immunogenic composition comprising the adjuvant.

Dascher et al teach immunization with a mycobacterial lipid vaccine comprising *Mycobacterium tuberculosis* lipids and DDA (see abstract and pg. 917 column 1 last paragraph). Dascher et al teach a vaccine against tuberculosis with DDA whereby the solution prepared was evaporated (see abstract and pg. 916 column 2 last paragraph) and used cholesterol as carrier lipids.

Ravindranath et al teach adjuvant-incorporated cell composition and methods for enhancing the antibody and T cell response to cellular antigens by incorporating an immunopotentiating agent into the cellular membrane or into an intracellular compartment to increase immune responses against. Ravindranath et al teach an adjuvant, wherein part or whole of cell of Mycobacterial species of phenolic glycolipids wherein the part of the apolar fraction of the lipid extract is glycosylated phenol phthiocerols, wherein said glycosylated phenol phthiocerols are phenolic glycolipids (see Table 1).

It would have been prima facie obvious at the time the invention was made to modify the adjuvant (disclosed by Lui et al) and to incorporate DDA (disclosed by Dascher et al) because the immune responses induced by the adjuvant DDA increases the efficiency of a TB (Tuberculosis) subunit vaccine (see Lindabald et al see abstract).

One would have a reasonable expectation of success because an adjuvant comprising a surfactant and an apolar fraction (as disclosed by Lui et al) is well known in the art.

Furthermore given that Ravindranath et al. teach useful adjuvants comprising whole or part of cell phenolic glycolipids that can be conjugated to cellular vaccines (see Table 1) and since the use phenolic glycolipids as adjuvants in vaccine compositions is known in the art leading to predictable results, it would be obvious to use cited phenolic glycolipids as taught by Ravindranath et al. into the adjuvant as taught by Liu et al. Thus, it remains obvious to combine them (Ravindranath et al. and Liu et al), even without an express statement of motivation. KSR forcloses the argument that a specific teaching, suggestion, or motivation is required to support a finding obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip

op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

14. Claims 1, 6-7, 9, 11, 13, 15, and 18-25 rejected under 35 U.S.C. 103(a) as being unpatentable by Liu et al (US Patent Application 20020044951 Date April 18, 2002), Dascher et al (International Immunology Vol. 15, No. 8, January 2003 pgs. 915-925), Anderson et al (US Patent Application 20020176867 Date November 28, 2002), and Lindbald et al (Infection and Immunity Vol. 65 No. 2, 1997 pgs. 623-629).

The claims are drawn to an adjuvant comprising dimehtyldioctadecylammonium-bromide, -chloride, -phosphate, or -acetate (DDA) and an apolar fraction or part of the apolar fraction of a total lipid extract of a mycobacterium (claim 1), a vaccine comprising the adjuvant (claim 6), wherein said vaccine is formulated for parenteral, oral or mucosal administration (claim 7), wherein the antigenic component comprises an ESAT6-Ag85B hybrid or a fragment thereof (claim 9), a delivery system comprising the adjuvant (claim 11), wherein said mycobacterium is *BCG, M. microti, M. tuberculosis or M. vaccae* (claim 13), wherein said mycobacterium is selected from the group consisting of *M. tuberculosis, M. bovis and M. africanum* (claim 15); an immunogenic composition comprising an adjuvant and a tuberculosis antigen, wherein said adjuvant comprises a solution prepared from an evaporated mixture of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent (claim 18); wherein said tuberculosis antigen comprises ESAT6-Ag85B hybrid or a fragment thereof (claim 19); an adjuvant consisting essentially of a resuspension of an evaporated mixture of a solvent, a surfactant selected from the group consisting of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent (claim 20); comprising a tuberculosis antigen (claim 21), wherein said tuberculosis antigen comprises ESAT6-Ag85B hybrid or a fragment thereof (claim 22), wherein surfactant is DDA (claim 23); an immunogenic composition comprising dimehtyldioctadecylammonium-bromide, -chloride, -phosphate, or -acetate (DDA) and an apolar fraction or part of the apolar fraction of a total lipid extract of a mycobacterium, wherein said

composition comprises an antigenic component comprising an antigenic epitope (claim 24), an immunogenic composition comprising the adjuvant (claim 25).

Liu et al teach an adjuvant comprising cationic surfactants and an apolar fraction or part of total lipid extract of a mycobacterium (see abstract, [0031], [0059]). Lui et al teach a vaccine comprising the adjuvant, wherein vaccine is formulated for parenteral, oral or mucosal administration (see 0048, 0054). Liu et al teach a delivery system comprising an adjuvant (see 0045). Liu et al teach composition comprising an antigen isolated from *M. tuberculosis* (see abstract). Liu et al teach an adjuvant wherein mycobacterium is *M. tuberculosis* (see claims).

Lui et al does not teach an adjuvant comprising dimehtyldioctadecylammonium-bromide, -chloride, -phosphate, or -acetate (DDA), an immunogenic composition comprising dimehtyldioctadecylammonium-bromide, -chloride, -phosphate, or -acetate (DDA) and an apolar fraction or part of the apolar fraction of a total lipid extract of a mycobacterium, wherein said composition comprises an antigenic component comprising an antigenic epitope, an immunogenic composition comprising the adjuvant, wherein the antigenic component comprises an ESAT6-Ag85B hybrid or a fragment thereof, an immunogenic composition comprising an adjuvant and a tuberculosis antigen, wherein said adjuvant comprises a solution prepared from an evaporated mixture of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent, wherein said tuberculosis antigen comprises ESAT6-Ag85B hybrid or a fragment thereof ; an adjuvant consisting essentially of a resuspension of an evaporated mixture of a solvent, a surfactant selected from the group consisting of DDA, DODA, or DC Chol and an apolar fraction of a total lipid extract of BCG, M. microti, M. tuberculosis, M. vaccae, M. bovis or M. africanumand a solvent; comprising a tuberculosis antigen, wherein said tuberculosis antigen comprises ESAT6-Ag85B hybrid or a fragment thereof, wherein surfactant is DDA.

Dascher et al teach immunization with a mycobacterial lipid vaccine comprising *Mycobacterium tuberculosis* lipids and DDA (see abstract and pg. 917 column 1 last paragraph). Dascher et al teach a vaccine against tuberculosis with DDA whereby the solution prepared was evaporated (see abstract and pg. 916 column 2 last paragraph) and used cholesterol as carrier lipids.

Anderson et al teach 20020176867 a tuberculosis vaccine of immunodominant antigens ESAT-6 and Ag85B from Mycobacterium tuberculosis. Anderson et al teach a vaccine, wherein immunodominant antigens ESAT-6 and Ag85B from Mycobacterium tuberculosis (see abstract, claims, 0027, 0079, whole document in its entirety).

It would have been prima facie obvious at the time the invention was made to modify the adjuvant (disclosed by Lui et al) and to incorporate DDA (disclosed by Dascher et al) because the immune responses induced by the adjuvant DDA is efficient for a TB subunit vaccine (see Lindabald et al see abstract).

One would have a reasonable expectation of success because an adjuvant comprising a cationic surfactant an apolar fraction (as disclosed by Lui et al) is well known in the art.

It would have been prima facie obvious at the time the invention was made modify the composition to incorporate a tuberculosis vaccine of immunodominant antigens ESAT-6 and Ag85B from Mycobacterium tuberculosis (as disclosed by Andersen et al 20020176867) into a composition in order to take advantage clearing or controlling an infection with virulent bacteria.

Furthermore given that Anderson et al (2002/0176867) teach a tuberculosis vaccine comprising the immunodominant antigens ESAT-6 and Ag85B from *Mycobacterium tuberculosis*. The skilled artisan would have been motivated to use of said antigens in the compositions of Dascher et al. and Lui et al. in order to take advantage clearing or controlling an infection of the virulent bacteria (as disclosed by Anderson et al.) Moreover, since the use of immunodominant antigens ESAT-6 and Ag85B a vaccine composition is known in the art leading to predictable results, their use remains obvious even without an express statement of motivation. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (**http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf**).

Conclusion

15. No claims allowed.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner of Art Unit 1645
GAU 1645

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645